**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES,**

**BANGALORE, KARNATAKA.**



COMPLETED PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION IN [M.S.] *SHALYA TANTRA*

**A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF TRIPHALA VARTI (ANAL SUPPOSITORY) WITH BASE OF COCOA BUTTER AND DICLOFENAC SUPPOSITORY IN THEMANAGEMENT OF *PARIKARTIKA W.S.R. TO FISSURE-IN-ANO***

**BY**

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**SDM TRUST’S Ayurvedic medical college,**

**danigond POST-GRADUATE CENTRE AND PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE, DR. SIDDHANT NAGAR,**

**TERDAL – 587315**

**2022-2023**

**FROM:**

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Terdal-587315, Karnataka

**TO**

**THE REGISTRAR,**

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES.

BANGALORE, KARNATAKA.

**THROUGH,**

**THE PRINCIPAL & HEAD OF THE DEPARTMENT OF *SHALYA TANTRA*,**

SDM Trust’s Ayurvedic Medical College,

Danigond Post-Graduation Centre,

Padma Ayurvedic Hospital and Research Centre,

Terdal-587315, Karnataka.

Respected Sir/ Madam,

**SUBJECT** – Submission of completed proforma for the registration of synopsis for the Dissertation work in MS (Ayu)

I request you to kindly register the below mentioned subject in my name for submission of dissertation to Rajiv Gandhi University of Health Sciences, Bangalore as the partial fulfillment for the award of the Degree M.S(Ayu) in *SHALYA TANTRA*.

**TITLE:- “A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF TRIPHALA VARTI (ANAL SUPPOSITORY) WITH BASE OF COCOA BUTTER AND DICLOFENAC SUPPOSITORY IN THEMANAGEMENT OF *PARIKARTIKA W.S.R. TO FISSURE-IN-ANO”***

Here with, I am enclosing the completed Proforma for Registration of the Dissertation subject.

Thanking you,

Place: TERDAL Yours Sincerely,

Date: (Dr. PRINCE KIRTONIA)

**Rajiv Gandhi University of Health Sciences, Karnataka, Bangalore**

**annexure-ii**

**PROFORMA FOR THE REGISTRATION OF SUBJECT FOR DISSERTATION**

|  |  |  |
| --- | --- | --- |
| **1. Name of the Candidate & Address** | **:** | Dr. PRINCE KIRTONIA  VIL./POST :- HANSUA  DIST. VIDISHA (MP) 464001 |
| **2. Name of the Institution** | **:** | SDM TRUST’s AYURVEDIC MEDICAL COLLEGE,  DANIGOND POST GRADUATION CENTRE,  PADMA AYURVEDIC HOSPITAL AND RESEARCH CENTRE, TERDAL KARNATAKA-587315 |
| **3. Course of Study and Subject** | **:** | M.S. (SHALYA TANTRA) |
| **4. Date of Admission of Course** | **:** |  |
| **5. Title of Topic** | **:** |  |
| **“A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF TRIPHALA VARTI (ANAL SUPPOSITORY) WITH BASE OF COCOA BUTTER WITH DICLOFENAC SUPPOSITORY IN THEMANAGEMENT OF *PARIKARTIKA W.S.R. TO FISSURE-IN-ANO*”** | | |

**6.BRIEF RESUME OF THE INTENDED WORK:**

**6.1NEED FOR THE STUDY**

Parikartika is a commonest and painful condition of anal canal. On the basis of *Lakshanas, Parikartika* can be correlated with Fissure-in-ano. It may be acute or chronic. *Parikartika* is mentioned in *Bruhatrayees* as the complication of *Basti1,2* and *Virechana Karma3,4,5*. *Parikartika* literal meaning is “*Parikartanvat Vedana*” i.e., cutting type of pain around anal region6. The factors responsible for causation of Parikartika are found in various texts as *Vamana -Virecana Vyapada, Basti Karma Vyapada, Upadrava of Atisara, Grahani, Arsa, Udavarta* etc7,8,9.

An Anal Fissure is a longitudinal split in the anoderm of the distal anal canal. Fissure occur most commonly in midline, posteriorly (90%) and much less commonly anteriorly (10%)10. It typically causes severe intolerable pain which is similar to excruciating pain in *Parikartika* as mentioned by *Acharya Sushruta11*.

According to classics, there are several treatment modalities like *Bhesaja Karma, Shashtra Karma, Kshara* *Karma.* Now a days treatments like use of laxatives, surgical procedures, some soothing ointment, V-Y advancement flap are done. Possibility of high recurrence, risk of formation of fistula or abscesses are seen.

In *Bhavprakasha Nighantu*, it was mentioned that *Triphala Churna* works like a *Sara Guna12.* In *Shodala Nighantu,* mentioned that work as a *Tridoshaghna, Sholabhinyase, Varnya, Shosha* and *Shophahara* properties14.

The different routes of drugs administration in the body but Rectal route the drugs absorption rate is very height. So Basti, Pichu, Varti (Anal Suppository) are use, theses procedure always a need for the assistance or help for the careful administration except varti. All of these practical difficulties can be avoided by using an appropriate the *Triphala varti* prepared by Cocoa Butter with molding method, which stays in the rectum for a stipulated period of time and also facilitates a quick absorption of the drug released15.

**6.2 REVIEW OF LITERATURE:**

1. **DISEASE REVIEW**

***PARIKARTIKA***

* In *Kashyapa Samhita,* it is mentioned as a V*yadhi* and classified into *Vataja, Pittaja* and *Kaphaja Parikartika21*.
* *Lakshana of Parikartika is explain in a Lakshana of Udavarta in Charaka Samhita*17,
* The *Nidana, Samprapti*, *Lakshanas and Chikitsa* of *Parikartika* are mentioned in *Sushruta Samhita11,2,*, *Charaka Samhita1,5,* and Ashtanga Hridyam4,.
* *Lakshana of Parikartika is explained in Astanga Hridayam as Poorva Roopa of Vataj Atisar and Arsha 16.*
* *Nidana and lakshan of Parikartika is explained in madhav nidan madhkosh comentry in the disease of grahini20.*

**FISSURE-IN-ANO**

* Comprehensive description of Fissure-in-ano, including its definition, etiopathogenesis, clinical features, investigations and treatment are explained in A concise book of surgery by S. Das, Bailey and Love’s Short Practices of Surgery and SRB Manual of Surgery.
* Fissure-in-ano is an elongated ulcer or crack in lower anal canal with, constipation, severe pain and streaks of blood along with stool during defecation23.

**2) DRUG REVIEW**

* Detailed description of *Triphala Churna*, its ingredients along with their properties and method of preparation are explained in *Bhaishajya Ratnavali24, Sushruta Samhita25*, *Ashtanga Hridyam26 and Bhaoprakasha Nighantu 27.*
* Majority of drugs in *Triphala Churna*  are having *Agnideepana* and *Rechana Guna* which will increase *Agni* in body and hence treat the cause of *Parikartika*.

**Ingredients of *Triphala Varti* are given below: -**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***S.No.*** | ***Drug Name*** | ***Latin Name*** | ***Rasa*** | ***Guna*** | ***Veerya*** | ***Vipaka*** | ***Karma*** | ***Part Used*** |
| 1. | Amalaki14 | Embilica officinalis | Amla,Kashaya Madhura Tikata , Katu, | Ruksha, Laghu, | Sheeta | Madhura | Tridosha Shamaka, Rasayana,  Deepana, | Phala, Beeja |
| 2. | Haritaki15 | Terminalia chebula | Kashaya Pradhana , Lavana varjita Pancha rasa | Ruksha, Laghu, | Ushna | Madhura | Tridosha Shamaka, Vrana shodhana, Ropana, Shothahara,  Deepana, | Phala, |
| 3. | Bibhitaki16 | Terminalia Bellerica | Kashaya, Tikta , Katu, | Ruksha, Laghu, | Ushna | Madhura | Tridosha Shamaka, Shothahara, Vedhna sthapana,  Deepana, | Phala, Beeja, |
| 4. | Cocoa butter | Theobroma oil | - | - | - | - | - | Oil |

***COCOA BUTTER:-***

* **Synonyms:-**
  + Theobroma oil, cocoa butter, cocoa beans, semina theobromatis.
* **Biological Source:-**
  + It is obtain from roasted seeds of Theobroma cacao Linn. Belonging to family *Sterculiaceae.*
* **Geographical Source:-**
  + Cocoa is cultivated in Brazil, Sri Lanka, Philippines, Curacao, Mexico, West Africa (Ghana, Nigeria) and some parts of India.
* **Characteristics**
  + Cocoa butter is yellowish white solid and brittle below 250 C. It has pleasant chocolate odour and taste.
  + It is insoluble in water but soluble in chloroform, petroleum ether, ether and benzene. Specific gravity ranges from 0.858 to 0.864, melting point between 300 C to 350 C, Refractive index varies from 1.4637 to 1.4578.
  + Cocoa butter is non-irritant to sensitive membrane tissues. It is also an excellent emollient and is used alone or in topical skin products for this property.
  + This makes it easy to pour suppositories before the base solidifies.
  + In many previous Research works in Ayurveda, cocoa butter has been used for the preparation of suppository.
* **Uses:-**
  + It is used as an emollient, as a base of suppositories and ointments, manufacture of creams and toilet soaps. It reduces the formation of stretch marks on skin and skin tissue. It is used as an ingredient in lotion bars, lip balms, body butters, soaps and belly balms for expectant mothers.

**PROCEDURE FOR PREPARATION OF DRUG:**

* The *Triphala* *Varti* will be prepared by adopting classical reference of *Varti Kalpana* given by *Acharya Sharangadhara*, as well as now a days modified suppository prepared by use the base of *Cocoa butter* with the ratio of *Triphala Churna & Cocoa butter* (melted by double boil method) is 1:2 , in the Department of *Rasa Shastra* & *Bhaishajya Kalpana*, Pharmacy SDMT’s Ayurveda Medical College and Hospital, Terdal.

* 1. **PREVIOUS RESEARCH WORKS DONE:**
* Suprabha D Hegde . management of Guda Praikatika (Fissure in Ano) with shalamlyadi lepa – A Clinical study – Shalya Tantra . Gov. Ayurvedic medical college Bangalore 2009.
* Geetanjali Hiremath . A study on the efficacy of Darvi Taila Matra Basti in the management of Parikartika with special reference to fissure in ano . Shalya Tantra. Shri Kalabyershwara Swamy Ayurvedic medical college hospital & research Centre, Bangalore
* Amit Kumar Sharma . A comparative study of peelu varti & Triphala Churna varti in the management of abhyantra Arshas. Shalya Tantra . N.K. jabashetty Ayurvedic medical college and PG Centre, Bihar . 2015
* Dr. Renhjith R. Warier . A comparative clinical study on efficacy of Triphala Churna Poorana and Aragwadhadi varti in the Management of Bhagandara (Fistula in Ano) . Shalya Tantra Ayurveda Mahavidyalaya Hubli.

**6.4 AIM AND OBJECTIVE OF THE STUDY:**

* To evaluate the effect of *Triphala Varti* in the management of *Parikartika* w.r.t. *Fissure in Ano*.
* To compare the efficacy of *Triphala Varti* and *Diclofenac suppository* in the Management of *Parikartika w.r.t. Fissure in Ano.*

**6.5 HYPOTHESIS**

* **Null Hypothesis**

**H0**- Per rectal suppository of *Triphala Varti* is not effective in the management of *Parikartika* w.s.r. to Fissure-in-Ano.

* **Alternative Hypothesis**

**H1** - Per rectal suppository of *Triphala Varti* is effective in the management of *Parikartika* w.s.r. to Fissure-in-Ano.

**H2 –** Per rectal suppository of *Triphala Varti* is more effective than the Diclofenac suppository in the management of *Parikartika w.s.r. to Fissure-in-Ano.*

**H3 –** Per rectal suppository of *Triphala Varti* is less effective than the Diclofenac suppository in the management of *Parikartika w.s.r. to Fissure-in-Ano*.

**H4 -** Per rectal suppository of *Triphala Varti* is equally effective the Diclofenac suppository in the management of *Parikartika w.s.r. to Fissure-in-Ano*.

**7. MATERIAL AND METHODS**

**7.1 MATERIALS:**

**SOURCE OF DATA**

1. **Literary source:**

* All relevant *Ayurvedic* and Modern literature text books regarding the disease and treatment will be reviewed and documented for the planned study.
* Relevant research articles, journals.

1. **Drug Source:**

Raw drugs will be procured from Herbal Garden and local market. After proper identification and authentication by Department of *Dravya Guna*, SDMT’s Ayurveda Medical College and Hospital, Terdal, *Triphala Churna*  *Varti* will be prepared as per classical guidelines in the Department of *Rasa Shastra* & *Bhaishajya Kalpana*, Pharmacy SDMT’s Ayurveda Medical College and Hospital, Terdal

1. **Sample source:**

Subjects fulfilling the inclusion criteria will be selected randomly from the OPD/IPD of Shalya Tantra and Medical camps organized by Padma Ayurveda Hospital & Research Centre, Terdal.

**7.2: METHOD OF COLLECTION OF DATA:**

Patients irrespective of gender, religion, socio-economic status, place, who are presented with classical sign and symptoms of *Parikartika,* will be selected for study.

**Study design**- A Single Arm Open Label Clinical Study.

**Sample size –** 40

**SELECTION CRITERIA**

**DIAGNOSTIC CRITERIA**

The diagnosis is based on subjective and objective criteria.

* Subjective :-
  + - Pain
    - Constipation
    - Burning sensation of anal region
* Objective :-
  + - Tenderness
    - Blood mixed stool passed
    - Ulceration in Anus

1. **INCLUSION CRITERIA:**

* Patient will be selected in the age group between 20-50 years.
* Patients with classical sign and symptoms of fissure in ano (*Parikartanvat Vedana, Daha, Sarakta-mala-pravrutti, Vatasangha, Mala-vastambha).*

1. **EXCLUSION CRITERIA**

* Patients suffering with any associated ano rectal disease like fistula-in-ano, polyps or piles.
* Any secondary fissures due to TB, Crohn’s disease, Ulcerative colitis, syphilis.
* Patient with immunocompromised status.
* Pregnant women.

**C) WITHDRAWAL CRITERIA**

* During the course of treatment if any serious ailments or serious adverse effect occurs and patient not following the instructions or patient himself/ herself wants to withdraw from the study such patients may be withdrawn from the study.

**DROP-OUTS**

* An attempt shall be made to record the reason for drop outs, if any during the clinical trial.

**D) INVESTIGATIONS**

* Blood Investigations - CBC, BT, CT
* RBS, HIV I & II, HBsAg in suspected cases.

**RESEARCH/ STUDY DESIGN:**

**METHODOLOGY:**

Enrollment of the 40 subjects, for the comparative clinical study with pre and post test criteria. Consent will be taken, then screening of the subject is done and the data will be recorded specially in two group prepared case report form with a complete history, examination and necessary assessments.

|  |  |  |
| --- | --- | --- |
| S. No. | Group | Drug |
| 1. | Trail group | Triphala Churna varti (Rectal suppository). |
| 2. | Controlled group | Diclofenac Rectal suppository. |

**INTERVENTION:**

|  |  |
| --- | --- |
| Route of suppository | Per Rectal |
| Sample size | 40 |
| Medicine | *Triphala Varti* |
| Dose | 1 (2gm) |
| Duration of drug intervention | 2 times for 14 days |
| Assessment will be done on | 0th ,7th ,14th, days |
| Follow Up | 7th and 14th days |

**PROCEDURE:**

* Procedure will be explained to the patient and consent will be taken.
* Patient will be made to lie down in left lateral position.
* Inspection, palpation was done by Digital examination.
* Under all aseptic precautions, lubricated Suppository containing *Triphala Varti* will be gently passed through the anus of patient and *Varti* will be instilled.
* Post procedure, patient will be advised for rest in bed for 15 min.

**ADVERSE DRUG REACTION:**

* If there is any ill effect of drug during treatment it will be stopped administering immediately and patient will be treated according to symptoms.
* An attempt shall be made to know the cause of adverse reaction and will be recorded during clinical trial and same will be informed to ethical committee.

**E) ASSESSMENT CRITERIA**

Assessment will be done on the basis of subjective and objective criteria.

**SUBJECTIVE CRITERIA28,29**

* *Guda Gata Vedana* (Pain) - VAS scale29
* *Guda Gata Daha* (Burning sensation after defecation)
* *Guda Gata Rakta Srava* (Bleeding)

**OBJECTIVE CRITERIA30,10**

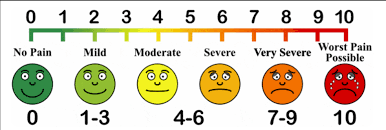
* Sphincter tonicity
* Ulceration in Anus

**F) ASSESSMENT PARAMETERS**

As per the REALISE SCORE questionnaire,

**SUBJECTIVE PARAMETER28**

1. ***Guda Gata Vedana* (Pain) - VAS scale29**



|  |  |
| --- | --- |
| **Grade** | **Pain** |
| **0** | No pain |
| **1-3** | Pain remains only during defecation |
| **4-6** | Pain remains 1-2 hours after defecation |
| **7-9** | Pain remains 4-6 hours after defecation |
| **10** | Pain remains 24 hours Very Severe pain |

1. ***Gudagata Daha* (Burning sensation after defecation)**

|  |  |
| --- | --- |
| **Grade** | **Duration** |
| **1** | Less than 1 hour |
| **2** | More than 1 hour and less than or equals to 2 hours |
| **3** | More than 2 hours and less than or equals to 3 hours |
| **4** | More than 3 hours and less than or equals to 4 hours |
| **5** | More than 4 hours |

1. ***Gudagata Rakta Srava* (Bleeding)**

|  |  |
| --- | --- |
| **Grade** | **Bleeding** |
| **1** | Never |
| **2** | Rarely, (less than or equals to 25% of defecations) |
| **3** | Sometimes, (more than 25% and less than or equals to 50% of defecations) |
| **4** | Often, (more than 50% and less than or equals to 75% of defecations) |
| **5** | Always, (more than 75% of defecations) |

**OBJECTIVE PARAMETER:30,10**

1. ***Sphincter Tonicity:*30,**

|  |  |
| --- | --- |
| **Grade** | **Sphincter Tonicity** |
| 0 | Index finger insertion to anal canal without any pain or discomfort |
| 1 | Able to admit index finger with tolerable pain (Hypotonicity) |
| 2 | Able to admit little finger with tolerable pain (Hypertonicity) |
| 3 | Able to admit little finger with tolerable pain |

1. ***Ulceration in Anus:* 10**

|  |  |
| --- | --- |
| **Grade** | **Site** |
| 0 | No tearing |
| 1 | Mucosal tearing less than 1cm |
| 2 | Mucosal tearing greater than 2cm |
| 3 | Tearing up to pectinate line |

**Statistical Analysis:**

Data will be collected using case report form (CRF) designed by incorporating all aspects (Ayurveda and modern science) for the study. Such collected data will be tabulated and analyzed using SPSS (Statistical package for social sciences) version 20 by using appropriate statistical test. Demographic data and other relevant information will be analyzed with descriptive statistics. Continuous data will be expressed in mean +/- standard deviation, and nominal and ordinal data will be expressed in percentage. Nominal & ordinal data will be analyzed using non parametric tests like Friedman’s test, Wilcoxon’s signed rank test, Chi-square test. Continuous data will be analyzed using parametric test like repeated measure ANOVA, Paired-t/ Unpaired-t test, as and when required. The changes (one tailed) with p value < 0.05 will be considered as statistically significant.

**7.3 Does the study require any investigations or interventions conducted on animals, patients or humans? (If so, describe briefly)**

Yes, the study requires interventions to be conducted on patients or human subjects. No animal experiment will be carried out.

**7.4. Has ethical clearance been obtained from your institution in case of 7.3?**

Ethical clearance will be obtained from Ethical Committee, SDM Trusts *Ayurvedic* Medical College & Hospital, Terdal for the above said clinical trial.

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| **9. SIGNATURE OF THE**  **CANDIDATE** | **:** |  |  |
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